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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,205	05/06/2004	Christopher E. Banas	6006-157	7254

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EXAMINER	
GANESAN, SUBA	
ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
12/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/840,205	BANAS ET AL.	
	Examiner	Art Unit	
	SUBA GANESAN	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/8/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3, 6-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 6-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/8/2009 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 1-3, 6-20 have been considered but are moot in view of the new ground(s) of rejection.

3. The rejection has been updated to address the new claim limitation that the ends of the prosthetic are corrugation-free and have suture holes.

4. Palmaz teaches the use of thin film stents with specific support structures. Casey teaches the use of selective corrugation placement to provide a prosthetic that is flexible in specified regions. Drasler has been utilized to specifically teach suture openings at the end of the prosthetic.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-3 and 13-15, 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) in view of Casey, II et al. (Pub. No.: US 2004/0019375) further in view of Drasler (6,287,335).

2. Palmaz et al discloses an implantable medical graft, comprising: a. a generally tubular body member comprising a film selected from the group consisting of metallic and pseudometallic materials (page 17, lines 1-7); and b. at least a portion of the body member having a plurality of undulations formed in walls of the body member by a support arranged in any manner as is known in the art of stent fabrication (page 5, lines 16-20, also see fig. 2 and 10, noting structural members 22 are thicker than the interstitial webs 24), and microperforations (e.g. Figs. 2-3 and 8A-8C).

3. However, Palmaz et al does not disclose the support arranged ***specifically*** as having continuous circumferential undulations. Casey II teaches a vascular graft structure with continuous circumferential undulations and undulation-free sections (see fig. 1) resulting in a prosthetic graft with strong and flexible walls. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the graft of Palmaz with areas of continuous circumferential undulations as taught by Casey II for the purpose of providing a strong and flexible graft wall.

Palmaz discloses several methods of fabricating the disclosed stent/graft, including deposition and etching. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine a thin film deposited graft with

unitary structural support members as taught by Palmaz with a specific pattern of structural support (ie an undulating structure) as taught by Casey II, since doing so would be a substitution of the structural members of Palmaz with the undulating structure of Casey II, both designs arriving at the same purpose: providing a stronger graft. Such a substitution of one known equivalent element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Palmaz in view of Casey lacks suture openings on an end of the graft. Drasler teaches the use of such openings (fig. 12A) for the purpose of securing and end support to the graft. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized sutures to secure an end support to the combination of Palmaz and Casey II. One of ordinary skill in the art would have further been motivated to provide suture openings to provide specific placement of sutures aid a surgeon in anchoring the prosthetic to a native blood vessel.

With respect to claim 2, Palmaz discusses selectively placing patterns of openings (figs. 8A-C). One of ordinary skill in the art would understand that the pattern can be selectively placed to achieve varying sites for cellular migration. Such a modification of Palmaz would have occurred using known methods and yielding predictable results. With respect to claims 4 and 18, Palmaz teaches portions of the graft without support members (see fig. 3).

With respect to claim 17, Palmaz in view of Casey discloses the circumferential corrugations as claimed. The resultant combination would be fully capable of bending in excess of 180 degrees about the longitudinal axis, since Palmaz discloses thin film

deposition, which results in a thin and flexible prosthesis, and Casey teaches the use of corrugations to increase flexibility (fig. 1).

4. Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) in view of Casey, II et al. (Pub. No.: US 2004/0019375) and Drasler (6,287,335) as applied above and further in view of Van Schie et al (6,974,471 B2).

5. Palmaz et al discloses an implantable medical graft as above. However, Palmaz et al does not disclose at least one suture member integrally extending along the longitudinal axis and through suture holes. Van Schie et al teaches an implantable medical graft comprising at least one suture member integrally extending along the longitudinal axis and through suture holes (e.g. Figs 4 and 6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of at least one suture member integrally extending along the longitudinal axis and through suture holes, as taught by Van Schie et al, to an implantable medical graft as per Palmaz et al, such that "the device can be curved in situ to fit the curved lumen" as found in Van Schie et al (col. 1, lines 44-52).

6. Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) in view of Casey, II et al. (Pub. No.: US 2004/0019375) and Drasler (6,287,335), further in view of Kula et al (6,325,825 B1).

7. Palmaz et al in combination with Casey II and Drasler teaches an implantable medical graft as above. However the combination lacks the thickness of the undulating regions as less than that of the non-undulating regions. Kula et al teaches an implantable medical graft having thicker ends, which correspond to the non-undulating regions of Palmaz et al/ Casey (col. 4, lines 60-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of an implantable medical graft having thicker ends, as taught by Kula et al, to an implantable medical graft as per Palmaz et al/ Casey, in order to "protect the artery and any plaque from abrasion that may be caused by the stent 10 ends during insertion of the stent 10. The modification also may provide increased radio-opacity at the ends of the stent 10. Hence it may be possible to more accurately locate the stent 10 once it is in place in the body" as found in Kula et al (col. 4, lines 60-66).

Regarding claim 7 Palmaz et al/ Casey in further view of Kula et al fail to disclose the **specific** thicknesses of the claimed regions. However, Palmaz et al discloses that the thickness of the microperforated material is approximately 10 micrometers (page 21, lines 13-14). Palmaz et al also discloses that the undulations may be formed by a "subtractive" method (Fig. 10). The reduction of the undulation region relative to the non-undulated region would result in a thickness of the thinner region *about* 3-7 micrometers.

8. With respect to claims 9 and 10, Palmaz et al/ Casey/Kula fail to disclose the suturing openings as cruciform or generally Y-shaped slots. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to make

the slots these shapes. Applicant has not disclosed that these shapes provides an advantage, is used for a particular purpose, or solve a stated problem, and therefore appear to be a matter of obvious design choice. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the holes of Drasler or the claimed slots because both allow for the passage of sutures. Furthermore such shaped holes for sutures are known in the art (Moser U.S. Pat. No. 5725556). Therefore, it would have been obvious to one of ordinary skill in the art to modify the cited references to obtain the invention as specified in claims 9 and 10. Please note that the Applicant may have intended to claim the microperforations as cruciform or generally Y-shaped slots.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) in view of Casey, II et al. (Pub. No.: US 2004/0019375) and Drasler (6,287,335) as applied above and further in view of Banas et al (5,749,880).

10. Palmaz et al discloses an implantable medical graft as above. However Palmaz et al does not disclose the implant having barbs. Banas et al teaches an implantable medical graft having projecting barb members (col. 14, lines 48-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of projecting barb members, as taught by Banas et al, to an implantable medical graft as per Palmaz et al, in order to aid in anchoring to the target blood vessel wall, as in Banas et al (col. 14, lines 48-54).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner, Art Unit 3774

/S. G./
Examiner, Art Unit 3774